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K092951

510(k) Summary in accordance with 21 CFR 807.92

DEC - 7 2009

Device Name:	Starlight Pro Silverlight
Type of 510(k) submission:	Traditional
Date of Submission:	September 22, 2009
Manufacturer:	Mectron Spa Via Loreto, 15, Carasco, GE 16042, Italy
FDA Registration Number:	3003933619
510(k) Owner:	Mectron Spa Via Loreto, 15, Carasco, GE 16042, Italy
510(k) Contact:	Roger Gray Vp, Quality and Regulatory Donawa Lifescience Consulting Piazza Albania, 10, 00153 Rome, Italy Tel: +39 06 578 2665 Fax: +39 06 574 3786
Trade name:	Starlight Pro Silverlight
Common Name:	Dental curing light
Class:	Class II
Product Codes:	EBZ
Classification Regulations:	21 CFR 872.6070: Ultraviolet Activator for Polymerization
Predicate device:	Translux Power Blue (K042199) – Heraeus Kulzer GmbH

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Device Description:

The Starlight Pro and Silverlight are dental curing light units intended for the polymerization of photo-hardening dental materials in the oral cavity.

A light emitting diode (LED) with a wavelength between 440 nm and 480 nm is used in both devices as the light source.

The spectrum of the light emitted by the LED corresponds to the absorption spectrum of camphorquinone photo-initiator, which is the most common and widely used visible light photo-initiator in among available photo-hardening dental materials.

Camphorquinone photo-initiator has an light absorption curve ranging approx. from 400 - 500 nm, with a peak absorption at approx. 468 nm.

This range falls within the emission spectrum of the LED used in the subject devices, making the units effective for the polymerization of camphorquinone-based dental materials.

The subject devices consist of a cordless handpiece, powered by a rechargeable battery, and incorporating a LED as light source, a battery charger unit and a fiber optic that directs the light onto the material being polymerized. The devices allow the user to activate two curing modes ('Fast' and 'Slow Rise') by pressing the relevant push-button on the handpiece. These two curing modes differ in the time of the light exposure and in the mode with which the light is emitted. In particular:

The fast curing mode has an exposure time of 10 sec. at the maximum light intensity.

The slow rise exposure mode has an exposure time of 20 sec. with a gradual increase of light during the first 3 seconds up to the maximum intensity.

Acoustic signal timings are emitted by the handpiece during the curing program execution

The charger unit allows recharging of the battery and it has an integrated light meter to check the light output. On the charger unit are three signaling LED lamps, indicating the on/off unit state, the battery charge state, and the functionality of the battery.

Intended use:
The Starlight Pro and Silverlight devices are dental curing light units intended for use in the oral cavity for the polymerization of photo-hardening dental materials that are activated in the 440 – 480 nm wavelength range..

Technological Characteristics and Substantial Equivalence:
The subject devices, Starlight Pro and Silverlight, are substantially equivalent to the predicate device 'Heraeus Translux Blue, cleared for US marketing under 510(k) reference K042199. The intended use, technological characteristics, operation, light source characteristics, and wavelength range of the emitted light of the subject devices are identical or very similar to the predicate device.

Both the subject devices, Starlight Pro and Silverlight, and the predicate device are designed for the polymerization of photo-hardening dental materials in the oral cavity.

All three devices consist of a battery charger unit and a cordless handpiece powered by an integral rechargeable battery, and incorporate a LED as light source and a removable fiber optic that directs the light on the material being polymerized.

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The operational principles of the subject devices and of the predicate device are identical. In all three devices, a monochromatic LED with identical spectral emission characteristics (wavelength 440 - 480 nm) is used as light source, and all three devices can perform two different curing modes, 'Fast' and 'Slow Rise'.

Both the subject devices, Starlight Pro and Silverlight, and the predicate device have a built-in light meter to measure the emitted light intensity.

Clinical Tests
No clinical testing was conducted

Non Clinical Tests
The following testing was conducted to evaluate the functionally and performance of the subject devices:

- Measurements of spectrum and irradiance
- Depth of cure (mm) on resin samples
- Software validation

The Starlight Pro and Silverlight comply with the electrical safety and electromagnetic compatibility requirements established by the standards EN IEC 60601 -1 and EN IEC 60601-1-2.

The results from these all these non-clinical tests confirm that the proposed devices are safe and effective for the polymerization of photo-hardening dental materials in the oral cavity.

Conclusion
The Starlight Pro, Silverlight and the predicate device share the same or very similar intended use, technological characteristics, operation, light source and wavelength of the emitted light.

Differences existing between the subject devices and the predicate device are minor and do not affect the safety and effectiveness of the Starlight Pro and Silverlight.

Therefore, based on the information contained in this submission, we believe that the Starlight Pro and Silverlight are both safe and effective for their intended use and substantially equivalent to the predicate device already in interstate commerce within the U.S.A.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room W-O66-0609
Silver Spring, MD 20993-0002

Mectron S.p. A.
C/O Mr. Roger Gray
Vice President, Quality and Regulatory
Donawa Lifescience Consulting SRL
Piazza Albania 10
00153 Rome
ITALY

DEC - 7 2009

Re: K092951
Trade/Device Name: Starlight Pro and Silverlight
Regulation Number: 21 CFR 872.6070
Regulation Name: Ultraviolet Activator for Polymerization
Regulatory Class: II
Product Codes: EBZ
Dated: September 22, 2009
Received: September 24, 2009

Dear Mr. Gray:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please contact the CDRH/Office of Surveillance and Biometrics/Division of Postmarket Surveillance at 240-276-3464. For more information regarding the reporting of adverse events, please go to http://www.fda.gov/cdrh/mdr/.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Susan Runner, D.D.S.
Acting Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K092951

Indications for Use Statement

Indications for Use

510(k) Number (if known): Not known

Device Name: Starlight Pro and Silverlight devices

Indications for Use: The Starlight Pro and Silverlight devices are dental curing light units intended for use in the oral cavity for the polymerization of photo-hardening dental materials that are activated in the 440 – 480 nm wavelength range.

Prescription Use (Part 21 CFR 801 Subpart D)	☒	AND/OR	Over-The-Counter Use (21 CFR 801 Subpart C)	☐

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Kevin Mulay for HSR

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K092951